

REMARKS

The present Amendment is in response to the Office Action mailed January 7, 2005, in the above-identified application.

Applicants acknowledge and appreciate the Examiner's willingness to conduct a telephone interview in the present application on February 23, 2005. During the telephone interview, Examiner Priddy and the undersigned discussed the outstanding Office Action and the two references cited by the Examiner, namely U.S. Patent No. 5,250,689 to Schlöpfer et al. and U.S. Patent No. 6,077,262 to Schlöpfer et al. During the telephone interview, Examiner Priddy and the undersigned discussed the differences between the device disclosed in the present application and the teachings of the Schlöpfer references. In addition, the undersigned proposed amending independent claims 1, 15, 16 and 24 to include the limitations noted above. Examiner Priddy and the undersigned reached a tentative agreement that the addition of the proposed limitations to the claims would distinguish the claims from the Schlöpfer references.

During the telephone interview, the Examiner also clarified that claim 34 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form to include all of the limitations of the base claim and any intervening claims. Examiner Priddy noted that claim 34 was listed in the Office Action as both a rejected claim and as an objected to claim.

Applicants note that U.S. Patent No. 6,565,565, which issued from parent Application No. 09/487,942, is involved in a litigation in the United States District Court for the Western District of Michigan-Northern Division. In the litigation, Pioneer Laboratories, Inc. is seeking a declaratory judgment of invalidity and non-infringement of the '565 patent. The '565

patent and the present application are commonly owned by Howmedica Osteonics Corporation.

In the Office Action, the Examiner objected to claims 6, 8, 19, 26 and 28 as having minor informalities. In response, claims 6, 8, 19, 26 and 28 have been amended as suggested by the Examiner. In view of the above noted amendments, Applicants respectfully assert that the claim objections have been overcome.

The Examiner rejected claims 6-8 under 35 U.S.C. §112, second paragraph, as being indefinite. In response, Applicants have amended claim 6 to change "the bottom surface" to --a bottom surface-- as suggested by the Examiner. In view of the above-noted amendment, Applicants respectfully assert that claims 6-8 now satisfy the requirements of 35 U.S.C. §112, second paragraph, and are otherwise allowable.

The Examiner rejected claim 15 under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,077,262 to Schläpfer et al. Referring to Fig. 2 thereof, Schläpfer discloses a spinal implant including a head portion 3a having a channel 6a extending therethrough that is adapted to receive a stabilizing rod. The spinal implant includes a closure 7a having two diametrically opposed studs 20, 21 projecting from a surface 19. After the closure 7a has been inserted in the head portion 3a, it is rotated so that the studs 20, 21 are inserted into the channels 24. In response to the Examiner's rejection, Applicants respectfully assert that independent claim 15 is unanticipated by the Schläpfer '262 patent because the cited reference neither discloses nor suggests a device including "a head portion" and "a fastener portion depending from the head portion, wherein the fastener portion is movable relative to the head portion when the locking cap is in the unlocked position and the fastener portion is fixed relative to the head portion when the locking cap is in the locked position." Clearly,

Schläpfer's head portion 3a is not movable relative to fastener portion 2a because it is rigidly attached to the fastener portion. For all of these reasons, claim 15 is unanticipated by the Schläpfer '262 patent and is otherwise allowable.

The Examiner rejected claims 1-6, 9, 13-14, 16-18, 20, 22-26, 32-33, 37 and 39 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,520,689 to Schläpfer et al. Referring to Fig. 1 thereof, the Schläpfer '689 patent discloses a fastening device including a fastener having a bottom portion that can be anchored in bone and an adjoining top portion 3 having a channel 4. The upper portion of the channel 4 forms a socket 6 having an interior face with interior threads 11. After a stabilizing rod 5 is secured within the channel 4, a fixation element having external threads 12 is tightened onto an exterior surface of the stabilizing rod 5 for locking the stabilizing rod in place. In response to the Examiner's rejection, Applicants respectfully assert that claim 1 is unanticipated by the Schläpfer '689 patent because the reference neither discloses nor suggests a device including a locking cap having "discontinuous opposed arcuate engagement flanges." One advantage of providing a locking cap with "discontinuous opposed arcuate engagement flanges" is discussed, *inter alia*, in paragraph 55 of the present application. As disclosed therein, the locking cap of the present application cannot be "over-torqued" which avoids the "damage often caused by over-tightening a conventional threaded locking mechanism, such as a set screw." In contrast, the Schläpfer '689 patent discloses an externally threaded set screw, which can be over-tightened. For all of these reasons, claim 1 is unanticipated by the Schläpfer '689 patent and is otherwise allowable. Claims 5-6, 9 and 13-14 are unanticipated, *inter alia*, by virtue of their dependence from claim 1, which is unanticipated from the reasons set forth above.

Independent claim 16 is also unanticipated for essentially the same reasons set forth above with respect to claim 1. Specifically, claim 16 is unanticipated by the Schläpfer '689 patent because the cited reference neither discloses nor suggests a device including "a locking cap having discontinuous opposed engagement flanges configured to cooperate with an interior camming surface of the channel" of the head portion. Claims 17-18, 20 and 22-23 are also unanticipated, *inter alia*, by virtue of their dependence from claim 16, which is unanticipated for the reasons set forth above.

Independent claim 24 is also unanticipated by the Schläpfer '689 patent for essentially the same reasons set forth above with respect to claim 1. Specifically, claim 24 is unanticipated because the cited reference neither discloses nor suggests a device including a head portion and a locking cap "including opposed arcuate engagement flanges configured for cammed reception in the opposed arcuate engagement slots of the head portion upon rotation of the locking cap relative to the head portion..., wherein each of the opposed arcuate engagement flanges extends only partially around the locking cap." Claims 25-26, 32-33, 37 and 39 are unanticipated, *inter alia*, by virtue of their dependence from claim 24, which is unanticipated for the reasons set forth above.

In the present Amendment, Applicants have added new claim 69 that depends from claim 1 and new claim 70 that depends from claim 16. The claims have been added to recite the limitation that the fastener and head portion are movable when the locking cap is in the unlocked position and are fixed relative to one another when the locking cap is in the locked position. Support for new claims 69 and 70 is found, *inter alia*, in paragraphs 67-71 of the present application.

In the present Amendment, Applicants have also added new claim 71, which includes all of the limitations found in

claim 18 of U.S. Patent No. 6,565,565. As noted above, the present application is a divisional of the application that issued as the '565 patent. New claim 71 also includes the recitation "wherein the upper portion and the lower portion of the locking cap are coupled together by an axial post that facilitates relative rotational movement of the upper portion relative to the lower portion." Support for this limitation is found in paragraph 66 of the originally filed specification.

In the Office Action, the Examiner indicated that claim 40 would be allowable if rewritten in independent form to include all of the limitations of the base claim and any intervening claims. In response, Applicants have amended claim 40 to be an independent claim that incorporates the limitations of previously presented claim 24 therein.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass the application to issue.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he telephone Applicants' Attorney at 908-654-5000 in order to overcome any additional objections which he might have.

Application No.: 10/091,708

Docket No.: SPINE 3.0-2153 CIP DIV

If there are any additional charges in connection with this requested Amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefore.

Dated: March 4, 2005

Respectfully submitted,

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